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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,708	09/20/2005	Tami Harel	34490	7428

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
09/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,708	HAREL ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,39-44,49-56 and 61-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,39-44,49-56 and 61-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/5/08; 3/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see paragraph 5 of page 1, filed 11 May 2009, with respect to the objection to claim 49 have been fully considered and are persuasive. The objection to claim 49 has been withdrawn.

2. Applicant's remaining arguments filed 11 May 2009 have been fully considered but they are not persuasive. Claims 34, 36, and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Findl'366. Claims 34-36 and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Klettner'617. Claims 1, 2, 6, 9, 16-19, 30, 33- 37, 39-44, 61-63 and 65 stand rejected, under 35 U.S.C. 102(e) as being anticipated by Houben et al. (US 5,919,216, hereinafter Houben'216).

3. Regarding Findl'366 and Klettner'617, Applicant simply argues that the claimed invention calls for an implanted electrode. It is noted that the electrodes of each of Findl'366 and Klettner'617 are capable of being implanted, and that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

4. Applicant also argues that Findl'366 and Klettner'617 do not teach or imply any electrode, but concurrently submit that each of Findl'366 and Klettner'617 does disclose generating an electric field, which inherently is done with a structure that can be considered an electrode.

5. In response to applicant's argument that the references teach away from certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., allowing monitoring in ambulatory patients) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Regarding Houben'216, Applicant argues that for at least claim 34 Houben'216 fails to disclose circuitry which reduces or prevents a substantial increase in insulin secretion. Initially, it is noted that this limitation is presented as functional language and the structure of Houben'216 is clearly capable of performing said function to read on the claim. Additionally, it is noted that the limitation is clearly and explicitly disclosed in the Abstract; column 2, line 55 through column 3, line 8; column 3, lines 33-42; column 7, lines 22-25; column 9, lines 45-67; and Figures 6 and 8A, wherein insulin secretion is modified, delayed or inhibited in order to maintain proper glucose/insulin kinetics.

7. It is noted that the limitation being argument being presented by Applicant relating to claim 34 is not even claimed in any of claims 1, 30 or 61 to present the same argument mutatis mutandis, and therefore all such arguments are considered moot.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 34, 36, and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Findl et al. (US 4,428,366, hereinafter Findl'366).

Regarding claims 34 and 36, Findl'366 discloses an apparatus for blood glucose control (TITLE) comprising at least one electrode capable of implantation (Fig. 1, coils 24 and 26) for applying an electric filed to a pancreas (column 3, lines 62-64); and circuitry configured to electrify said electrode in a manner which compensates for a loss of acute response by said pancreas by significantly reducing glucose levels in a non-insulin manner (ABSTRACT; column 2, lines 45-63), the device inherently configured to apply said field when glucose levels are not elevated as well as when elevated.

Further regarding claim 34, it is noted that the limitation of preventing a substantial increase in insulin secretion is a recitation of the intended use of the claimed invention. Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 40, Findl'366 discloses an apparatus programmed with knowledge of a slow acting chemical-based insulin therapy provided to said pancreas (column 2, lines 14-21; column 7, lines 39-51).

10. Claims 34-36 and 40 stand rejected under 35 U.S.C. 102(b) as being anticipated by Klettner (US 5,031,617, hereinafter Klettner'617).

Regarding claim 34, Klettner'617 discloses an apparatus for blood glucose control (TITLE) comprising at least one electrode capable of implantation and adapted to apply an electric field to the pancreas (ABSTRACT; column 2, line 36); and circuitry configured to electrify said electrode in a manner which compensates for a loss of acute response by said pancreas ((ABSTRACT; column 1, lines 39-55; column 2, lines 34-45).

Further regarding claim 34, it is noted that the newly amended limitation of preventing a substantial increase in insulin secretion is a recitation of the intended use of the claimed invention. Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 35, Klettner'617 discloses that some applications might increase insulin production, which inherently would be quantifiable as a bolus.

Regarding claim 36, Klettner'617 discloses that glucose levels are reduced in a non-insulin manner, wherein a non-insulin manner is taken to mean a therapy in which insulin is not injected into the system.

Regarding claim 40, Klettner'617 discloses an apparatus programmed with knowledge of a slow acting chemical-based insulin therapy provided to said pancreas (column 2, lines 34-51),

11. Claims 1, 2, 6, 9, 16-19, 30, 33- 37, 39-44, 61-63 and 65 stand rejected, under 35 U.S.C. 102(e) as being anticipated by Houben et al. (US 5,919,216, hereinafter Houben'216).

Regarding claims 1, 30, 33, 34, and 61, Houben'216 discloses an apparatus and method for blood glucose control (TITLE) comprising a least one implanted electrode adapted to apply an electric field to affect a pancreas (ABSTRACT); and circuitry adapted to electrify said electrode in a manner which compensates for loss of acute response by said pancreas (ABSTRACT). Houben'216 discloses reducing or preventing substantial increase in insulin secretion during treatment (column 3, lines 33-42; column 9, lines 45-67).

Regarding claim 2, Houben'216 discloses an additional stimulation method for increasing insulin (abstract).

Regarding claim 6, electrical stimulation would inherently affect the nervous tissue of the stimulated area.

Regarding claims 9, 62 and 65, the pulses disclosed in Houben'216 are considered to read on a short duration of time.

Regarding claims 16-19 and 63, and further regarding claim 57, Houben'216 discloses an ingestion event (column 8, line 54, through column 9, line 15).

Regarding claim 35, Houben'216 discloses secretion of insulin in a quantity inherently quantifiable as a bolus.

Regarding claims 36 and 37, it is noted that the limitations of reducing glucose and glucagon levels are a recitation of the intended use of the claimed invention.

Intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 39, Houben'216 discloses applying control of insulin levels for at least 20% of ingestion events (Figs. 3, 7A&B and related paragraphs).

Regarding claim 40, Houben'216 discloses a slow acting chemical-based insulin therapy provided to said pancreas (ABSTRACT).

Regarding claims 41-44, Houben'216 discloses an automatic ingestion and glucose sensor for automatically detecting an event requiring an acute insulin response (Fig. 7A and related paragraphs).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 34-37, 39-44 and 49-56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-55 and 79-81 of copending Application No. 10/804,560. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to implant the electrode, the claims in both applications otherwise being directed to an apparatus for blood glucose level control.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-29 and 61-67 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 27-30 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to compare the increase to the regular insulin level response in the same person.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 30-33 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-38 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to reduce glucose levels in an acute manner.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 34-37, 39-44 and 53-56 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-49 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to use a non-excitatory electrical field when stimulating the pancreas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 49-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56-63 of copending Application No. 10/570,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 49 of the instant application simply requires that the electrode be implanted, which would be an obvious variation of the apparatus with electrode of non-disclosed location of claim 56 in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

24 September 2009

/George Manuel/
Primary Examiner